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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Hultgren et al.

Art Unit 1631

Serial No. 09/637,216

Filed August 11, 2000

For ANTI-BACTERIAL COMPOUNDS DIRECTED AGAINST PILUS BIOGENESIS,
ADHESION AND ACTIVITY; CO-CRYSTALS OF PILUS SUBUNITS AND
METHODS OF USE THEREOF

Confirmation No. 7884

Examiner Monika B. Sheinberg

#12
Plunkett
6/26/01

June 20, 2001

RESPONSE UNDER 37 C.F.R. §1.111

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS,
MADAM:

This letter is response to the Office action dated May 8, 2001, the time for response being extended by one (1) month to July 8, 2001.

Applicants respectfully request reconsideration under 37 C.R.F. §1.111 of the restriction requirement and examination of the application on the merits in view of the response as set forth herein. According to 35 U.S.C. § 121, a restriction is proper only if there are at least two independent **and** distinct inventions. Further, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."¹ No showing has been made by the Office that the search and examination of this entire application or, at least, something less than fourteen sets of claims can be made without serious burden.

¹ See MPEP § 803 (emphasis added).

One of the goals of the patent system is to put others on notice of a person's rights. Consistent with this goal, MPEP § 803 requires that as much subject matter be examined in one application as can be done without serious burden. With all due respect, dividing the subject matter of this application into fourteen separate groups will only serve to frustrate this goal and is contrary to MPEP § 803.

The Applicants hereby provisionally elect Group I claims (1-21) with traverse, for examination in the present application. Applicants respectfully request reconsideration of the restriction requirement and rejoinder of the claims of Groups II, III and XI for the reasons set out herein.

The Office action sets forth a restriction requirement under 35 U.S.C. § 121 to the following groups of claims: Group I (claims 1-21) claiming an isolated compound; Group II (claims 22-26) claiming compositions containing a mimic of an amino-terminal motif; Group III (claims 27-33) claiming compositions containing a mimic of pilus chaperone G₁ beta-strand; Group IV (claims 34-38) claiming methods of preventing or inhibiting formation of a pilus subunit-subunit structure in a subject; Group V (claims 39-41) claiming methods of preventing or inhibiting formation of a chaperone-subunit structure in a subject; Group VI (claim 42) claiming a method of preventing or inhibiting pili adhesion; Group VII (claims 43-49) claiming methods of treating a bacterial infection using a peptide or peptide analog according to formula (I); Group VIII (claims 50-55) claiming methods of treating a bacterial infection using a peptide or peptide analog according to formula (II); Group IX (claims 56-60) claiming methods of preventing or inhibiting biofilm formation; Group X (claims 61-65) claiming methods of inhibiting bacterial colonization; Group

XI (claims 66-79) claiming compositions comprising a pilus chaperone-subunit co-complex; Group XII (claim 80) claiming a method of crystallizing a PapD-PapK co-complex; Group XIII (claims 81-122) claiming methods of identifying an antibacterial compound using a three dimensional structural representation corresponding to a crystalline pilus chaperone-subunit co-complex or fragment thereof; and Group XIV (claims 123-135) claiming machine-readable media embedded with three dimensional structural representation corresponding to a crystalline pilus chaperone-subunit co-complex or fragment thereof.

Many of these groups are classified identically or nearly identically thereby indicating that the claims of several groups are directed to similar subject matter and as such, restriction is not proper.² Specifically, Groups I, II, III and XI are all classified in class 530, subclass 300 and Groups IV, V, VI, VII, VIII and IX are all classified in class 514, subclass 2. Groups I, II, III, XI, and XII are all classified in class 530 and Groups XIII and XIV are both classified in class 395. Thus, the claims as filed are classified in either class 514, subclass 2 (Groups IV-IX), class 530 (Groups I-III, XI and XII), class 395 (Groups XIII and XIV) or class 435 (Group X). This is consistent with the notion that the claims of this application are drawn to similar subject matter for which the search process would be overlapping for most of these claims.

The Office asserts that the grouping of claims are proper because the claims of Group I are directed to an isolated compound and the claims of Groups II, III and XI are directed to

² See MPEP 803.

compositions having varying critical features.³ However, several of the features of the claims of Groups II, III and XI are also features of the compounds as claimed in Group I. For instance, claim 8 of Group I and claim 22 of Group II are directed to a compound and a composition, respectively, which comprises a mimic of an amino-terminal motif of a pilus subunit with at least two alternating hydrophobic amino acid residues. Similarly, claim 4 of Group I and claim 27 of Group III are directed to a compound and a composition, respectively, comprising a mimic of a chaperone G₁ beta-strand with at least two alternating hydrophobic amino acid residues. Claim 66 of Group XI is directed to a composition comprising an amino acid sequence of a chaperone G₁ beta-strand and an amino acid sequence of an amino-terminal end of a pilus subunit. Further, claim 12 of Group I and claim 24 of Group II are directed to a compound and a composition, respectively, which comprises a 10 to 20 residue peptide or peptide analog according to formula (I). Claim 16 of Group I and claim 29 of Group III are directed to a compound and composition, respectively, comprising a 7 to 17 peptide or peptide analog according to formula (II). Accordingly, a search of the claims in Group I would, without question, uncover art pertinent to the claims of Groups II, III and/or XI.

Applicants urge that the claims of Groups I, II, III and XI are related to the extent that restriction is improper under MPEP 808.02. The claims of Groups I-III and XI have the same classification (*i.e.*, are all classified in class 530, subclass 300), the same status in the art and the same field of search. Accordingly, the restriction requirement with respect to Groups

³ See Office action at page 4.

I-III and XI does not satisfy 35 U.S.C. §121. As set out above, the claims in Groups I-III and XI contain subject matter which is closely related and as such, the same search could be conducted to examine all of Group I-III and XI claims. Accordingly, Applicants respectfully urge that the claims of II, III and XI be rejoined for prosecution.

For each of the reasons set forth above, reconsideration of the restriction requirement and rejoinder of the claims of Groups II, III and XI is respectfully requested. Applicants reserve the right to file divisional applications directed to the non-elected claims of Groups IV-X and XII-XIV. Additionally, in the event that the Examiner does not allow rejoinder of Groups II, III and XI, Applicants also reserve the right to file divisional applications directed to the non-elected claims of these groups.

Election of Species

The Office is further requiring an election of species for prosecution of the Group I claims (claims 1-21). Applicants are required to elect two species, one for each of the following:

- (A) peptide or non-peptide compounds; and
- (B) a specific Gram-negative bacterium.

With regard to species election (A) above, Applicants elect the peptide compounds for purposes of examination. Claim 1 is said to be generic.⁴ The Group I claims that read on the above elected peptide species are claims 1, 2, 4-19. In conjunction with the election of the peptide compound species, the Office is requiring the subspecies election of either a compound of the formula (I) or a compound of the formula (II). Applicants elect

⁴ See Office action at page 5.

compounds of formula (I) for examination, with traverse. The Group I claims that read on the above elected subspecies are claims 8-15. The Office is further requiring the election of a particular peptide sequence and Applicants elect SEQ ID NO: 12, with traverse. The Group I claims that read on the above elected sequence are claims 9 and 14. The claims of Group I (claims 1-21) are **all** generally directed toward compounds which will bind to a pilus subunit groove thereby exhibiting antibacterial activity against Gram-negative bacteria. As such, the species and subspecies are sufficiently related that the simultaneous search and examination of all species in these claims will place no undue burden on the Examiner.

With regard to species election (B) above, Applicants respectfully submit that the election requirement is improper. The compounds of the present invention exhibit antibacterial activity against Gram-negative bacteria and do not exhibit specific antibacterial activity against individual Gram-negative bacterium as recited in claims 7, 11, 15, 19 and 21 i.e., if several strains of Gram-negative bacteria are present in an organism or sample, the compounds exhibit antibacterial activity against all strains of Gram-negative bacterium present.

Further, Applicants urge that the search of these species can be done without undue burden to the Examiner because claims 7, 11, 15, 19 and 21 further limit the claim from which each claim respectively depends (claims 4, 10, 12, 16 and 20, respectively). Claims 4, 10, 12, 16 and 20 recite that the compound exhibits antibacterial activity against a Gram-negative bacterium. The species listed by the Office are specific Gram-negative bacterium.

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Subject to the foregoing traverse, Applicants elect *Escherichia coli* for examination. The Group I claims that read on the above elected species are claims 4, 7, 10, 11, 12, 15, 16, 19, 20 and 21.

Enclosed is a check for \$55.00 to cover the fee for the one (1) month extension of time. Any fee deficiency or overpayment connected with this response may be charged to Deposit Account No. 19-1345. If the Examiner has any questions, she is invited to contact the undersigned.

Respectfully Submitted,



Karen Y. Hui, Reg. No. 44,785
SENNIGER, POWERS, LEAVITT & ROEDEL
One Metropolitan Square, 16th Floor
St. Louis, MO 63102
(314) 231-5400